

each of said plurality of patients ~~said patient~~; and

c) prior to ~~each of said consultations~~ interview, providing ~~said the~~ physician with said condition-specific information in computerized form regarding medical practices relating to said one or more medical conditions applicable to each of said plurality of patients ~~said patient~~, thereby clinically educating ~~said the~~ physician with updated medical practices relating to said one or more of a plurality of medical conditions.

## REMARKS/ARGUMENTS

### A. In the Specification

1. Ten (10) separate paragraphs have been amended in the specification to clarify previously disclosed matter and/or correct language, reference labeling, figure description, and/or syntax. No new matter has been added.

### B. In the Claims

1. Claims 1-32 are pending in this application. Claims 1-32 have been amended to correct language, syntax, avoid the citation of the prior art, and/or point out the specific features of Applicant's invention with greater clarity. No claims have been cancelled. No new claims have been added. No new matter has been added.

### *Regarding the Claim Rejections under 35 U.S.C. 102*

2. Applicant acknowledges the quotation of the appropriate paragraph of 35 U.S.C. 102 that forms the basis for the rejections under this section made in the office action.

3. Claims 1-6, 8-13, 16, and 24-32 have been rejected under 35 U.S.C. 102(b) as being anticipated by Joao (6,283,761; hereinafter Joao). Applicant respectfully disagrees with the anticipation rejection in light of the amendments to claims 1-6, 8-13, 16, and 24-32 and the

arguments presented below. Applicant now believes that claims 1-6, 8-13, 16, and 24-32 are in condition for allowance.

(A) As per claim 1, Joao does not disclose a method for creating a medical chart regarding a patient's medical condition for which an appointment has been scheduled with a physician, including the steps of: providing a patient with access information for logging onto a server site containing a plurality of patient files including a patient file for the patient, providing and enabling a condition-specific interview for the patient regarding the patient's medical condition wherein the content and amount of interview questions can be dynamically altered depending upon responses provided by the patient, logging onto said server site by the patient, or conducting said condition-specific interview with the patient by said server site wherein the content and amount of interview questions can be dynamically altered depending upon responses provided by the patient.

Joao discloses a method whereby the provider, not the patient, is meant to access the central processing computer and enters data and/or information regarding the patient. (Joao: col. 25, lines 10-13). Even if information is needed from the patient, the patient enters the information via the provider's communication device. (Joao: col. 25, lines 19-22). Because the patient is using the provider's communication device, for which the provider will want to maintain strict security measures to protect the information contained in other patient files, the patient will not have access information for logging onto the provider's communication device. Therefore, Joao does not require the patient to have access information for logging onto a server site or that the patient actually log onto the server. Applicant's invention discloses a system whereby the patient is given access information to enable the patient to gain system access via the patient's communication device. Not only does this allow the patient to access the system at the time and location of the patient's choice, it also saves the physician or provider from having to spend time and effort and use limited office space to gather this information.

Additionally, Joao does not disclose the step of providing a condition-specific interview

for the patient by the server site wherein the content and amount of interview questions can be dynamically altered depending upon responses provided by the patient. Joao discloses information that can be

“obtained from the various patients, individuals, providers, payers, and/or intermediaries, who or which utilize and/or who or which are serviced by the present invention. For example, the respective patients, providers, payers, intermediaries, and/or other users, could fill out questionnaires, forms, narratives, claim forms, and/or any other information medium, in written form, electronically, and/or otherwise.” (Joao: col. 19, lines 57-64).

While Joao discloses the ability to gain general information from patients, Joao does not disclose the step of providing an interview that is specific to the medical condition of the patient. The invention disclosed in Joao is primarily for the purpose of electronically generating medical diagnosis over an electronic network. Applicant's invention involves patient-data-capture aimed at producing a complete and reproducible history at a specialist's level from which the physician works to improve the office visit. Applicant's invention discloses a system wherein the content and number of questions in the interview is partially based on responses given by the patient to specific questions. The present invention contains structured clinical interviews that are created by specialty physicians using a template that sets the order but not the content of the questions. Each interview is specific to a particular problem and the content can be modified based on the age and gender of the patient. For instance, an abdominal pain interview is different for a male vs. a female, and a hip pain interview is different for a twelve year old vs. a sixty year old. As an additional example, in response to an answer that indicates a patient is left-handed, the subsequent interview questions that relate to hand injuries will involve specific queries relating to the left hand as opposed to the right hand. This dynamic interview process, not disclosed in Joao, saves the amount of time and effort needed by the provider to gain specific information about the patient regarding the patient's medical condition, while providing the physician a very complete and accurate history of the patient's condition in an electronic format.

Additionally, Joao does not disclose the ability of the provider to enable a condition-specific interview for the patient. As discussed above, Joao does not disclose a condition-specific interview by the provider. Therefore, the provider cannot enable the patient to complete a condition-specific interview. At most, Joao discloses a general form or questionnaire that must be filled out by the patient at the provider's office. Applicant's invention discloses a system wherein the provider, after obtaining preliminary information by the patient regarding the patient's medical condition, can access the system and select (enable) an appropriate interview for the patient to complete. In Applicant's invention, the patient can then log onto the MI system and complete the interview at the time and location of the patient's choice.

Furthermore, the unique direct patient-data-capture capability of the present invention has solved a major problem that has always plagued the electronic medical record industry – the necessity of the physician to become a computer data entry person. Having the vast majority of the specific clinical history captured electronically from condition-specific interviews before a visit frees the physician from this repetitive and time consuming task and allows him or her to concentrate on the patient. The routine “dumbing down” of the patient's historical information - an additional side effect encountered in physician-data-entry of electronic records - is also solved by the present invention, as the details related to the particular patient's reason for the visit are completely and accurately electronically transferred to the physician as described by the patient. This has the dual effect of increasing the amount of time the physician can spend with the patient, as the generally sixty to seventy percent of a complete office visit spent on gathering historical information from the patient is eliminated, and providing more thorough documentation for the physician when examining the patient.

Therefore, as it is Applicant's belief that, as amended, claim 1 of the present invention is not anticipated by Joao, Applicant believes that claim 1 is now in condition for allowance.

(B) As per claim 2, because claim 2 is dependent on claim 1, Applicant believes that claim 2 is now in condition for allowance in light of the amendment to claim 1.

(C) As per claim 3, claim 3 was amended to include language clarifying the process of generating the electronic physician report, wherein the system converts information responsive to said condition-specific interview from language not containing technical medical terminology into language containing technical medical terminology. Joao discloses neither the ability to convert language not containing technical medical terminology obtained from a condition-specific interview into language which is in proper medical terminology to assist the physician in treating the patient. Applicant's invention is further distanced from Joao in the respect that Applicant's system can transmit the physician report to the physician in a format in which a physician is normally accustomed to receiving such information. Therefore, Applicant's invention is not anticipated by Joao. Furthermore, because claim 3 is dependent on claim 1, Applicant believes that claim 3 is now in condition for allowance in light of the amendment to claim 1.

(D) As per claim 4, because claim 4 is dependent on claim 3, and claim 3 is dependent on claim 1, Applicant believes that claim 4 is now in condition for allowance in light of the amendment to claim 1.

(E) As per claim 5, claim 5 was amended to include the steps of electronically generating pre-visit information that includes a pre-visit patient summary responsive to said condition-specific interview including information relating to the patient's medical condition, and transmitting said pre-visit patient summary to the patient in language not containing technical medical terminology. Joao neither discloses nor suggests generating pre-visit information responsive to a condition-specific interview or transmitting the pre-visit patient summary to the patient in language not containing technical medical terminology. Furthermore, because claim 5 is dependent on claim 1, Applicant believes that claim 5 is now in condition for allowance in light of the amendment to claim 1.

(F) As per claim 6, although Joao discloses an apparatus that can be used to automatically generate several types of communications (see col. 11, lines 7-13), Joao does not

“describe herein” the generation of key questions relating to the patient’s medical condition for the patient to ask the physician. Applicant’s invention discloses a system that can generate key condition-specific questions for transmittal to the patient before the visit with the physician. These questions are presented to the patient in language which is easily comprehensible by the patient. The patient can then, when visiting with the physician, ask the physician these questions to gain more knowledge and information about the patient’s condition. Thus, claim 6 is not anticipated by Joao. Further, because claim 6 is dependent on claim 1, Applicant believes claim 6 is in condition for allowance in light of the amendment to claim 1.

(G) As per claim 8, claim 8 was amended to include the language of generating a post-visit patient report in language not containing technical medical terminology. Such a report was neither disclosed nor suggested in Joao. Furthermore, because claim 8 is dependent on claim 1, Applicant believes that claim 8 is now in condition for allowance in light of the amendment to claim 1.

(H) As per claim 9, claim 9 was amended to include language clarifying the condition-specific nature of both the interview and questions generated. Claim 9 was also amended to clarify the non-technical language in which the patient questions are generated. Both of these features are neither disclosed nor suggested in Joao. Furthermore, because claim 9 contains the same limitations as claims 3, 5, and 7, and claims 3, 5, and 7 are dependent on claim 1, Applicant believes that claim 9 is now in condition for allowance in light of the amendment to claim 1.

(I) As per claim 10, because claim 10 has the same limitations as claim 4, and claim 4 depends on claim 3, which is dependent on claim 1, Applicant believes that claim 10 is now in condition for allowance in light of the amendment to claim 1.

(J) As per claim 11, claim 11 was amended to include the steps of providing a patient with access information for logging onto a server site and logging onto said server site by the patient using said electronic communication network. Joao does not disclose these steps. See paragraph 3A in this response. Therefore, Applicant believes that claim 11 is now in condition

for allowance in light of the amendment to claim 11.

(K) As per claim 12, because claim 12 is dependent on claim 1, Applicant believes that claim 12 is now in condition for allowance in light of the amendment to claim 1.

(L) As per claim 13, because claim 13 repeats the same limitations of claims 6 and 7, and claim 6 depends on claim 5, which depends from claim 1, Applicant believes that claim 13 is now in condition for allowance in light of the amendment to claim 1.

(M) As per claim 16, claim 16 involves a method of creating a medical chart regarding an office visit for a specific condition of a patient that includes the steps of storing the patient files without identifiers and using the patient files in medical studies. While Joao discloses a database that can be securely accessed by patients and providers, Joao does not disclose a database that allows patient files to be accessed without the person accessing the files knowing which file is being accessed. For example, Joao discloses how identification cards can be used to store pertinent information for any of the *respective* parties so as to provide the *respective* party with access to the various data. (Joao: col. 7, lines 18-23). The Joao system neither discloses nor suggests allowing users to non-discriminately access unidentified patient files for the purposes of performing medical studies. Applicant's invention discloses a system wherein a patient chart is created and stored in such a way that certain specified users can gain access to patient files for the purpose of performing medical studies without compromising the security of each patient's information.

Additionally, while Applicant acknowledges that Joao discloses that statistical calculations are contained in the database, Joao does not disclose or suggest a system for *performing* medical studies using a group of patient files. Joao discloses a database that contains statistical and/or mathematical information for assigning and/or correlating certain levels and/or estimates for any and/or all of the information generated by the central processing computer. (Joao: col. 19, lines 13-20). Joao does not disclose a system for *performing* medical studies using a group of patient files, as is claimed in Applicant's invention. Furthermore, because claim

16 is dependent on claim 11, Applicant believes that claim 16 is now in condition for allowance in light of the amendment to claim 11.

(N) As per claim 24, claim 24 was amended to include a system for providing a patient with access information for logging onto a server site containing a plurality of patient files including a patient file for the patient. Joao does not disclose a system that gives a patient access information for logging onto a server site that contains sensitive information about other patients. Applicant's invention discloses a method where a patient is given access information so that the patient can access the system at the time and place of their convenience. Therefore, Applicant believes that claim 24 is now in condition for allowance in light of the amendment to claim 24.

(O) As per claim 25, Applicant respectfully disagrees with the Examiner's conclusion that claim 25 is anticipated by Joao. Joao does not disclose a system for selecting and providing a plurality of key condition-specific physician questions to said patient with said pre-visit summary. As discussed in paragraph 3A of this response, Joao includes the ability for patients who use a provider's communication device to input information into the central processing system. However, Joao does not disclose a system that can select from a particular set of questions depending on the input from the patient. Applicant's invention discloses a system whereby the patient's responses to particular interview questions can dynamically alter content and quantity of the questions generated by the system and transmitted to the patient in the pre-visit summary. Thus, claim 25 is not anticipated by Joao. Further, because claim 25 is dependent on claim 24, Applicant believes that claim 25 is now in condition for allowance in light of the amendment to claim 24.

(P) As per claim 26, because claim 26 is dependent on claim 24, Applicant believes that claim 26 is now in condition for allowance in light of the amendment to claim 24.

(Q) As per claim 27, Applicant respectfully disagrees with the Examiner's conclusion



that claim 27 is anticipated by Joao. Claim 27 includes "a system for electronically selecting condition-specific educational material to be provided to said patient, and transmitting said selected material to said server site for storage in said patient's file." Joao does not disclose a system that electronically selects condition-specific material to be provided to a patient. Rather, Joao a process whereby the doctor, after obtaining the diagnosis or possible diagnoses, can review the diagnostic report and choose a final diagnosis and/or treatment plan. (Joao: col. 25, lines 54-62). While Applicant acknowledges that a final treatment plan can include the selection of material for a patient, Joao discloses this choice to be made by the doctor, not electronically by a system. Applicant's invention includes a method whereby the MI system has the capability to electronically generate educational material specific to the patient's medical condition, and then transmit this educational material to the patient's file for access by the appropriate parties. Thus, claim 27 is not anticipated by Joao. Further, because claim 27 is dependent on claim 24, Applicant believes that claim 27 is now in condition for allowance in light of the amendment to claim 24.

(R) As per claim 28, because claim 28 is dependent on claim 24, Applicant believes that claim 28 is now in condition for allowance in light of the amendment to claim 24.

(S) As per claim 29, Applicant respectfully disagrees with the Examiner's conclusion that claim 29 is anticipated by Joao. Joao discloses a system that can use identification cards to store pertinent information for any respective party and provide that respective party with access to various data. (Joao: col. 7, lines 16-23). Joao also discloses a system that can contain data and/or information that can restrict access by any of the providers, patients, or other users, to any of the data and/or information stored in the database. (Joao: col. 19, lines 8-11). While Joao discloses the security measures that can be used to protect patient information, Joao does not expressly disclose a system whereby a physician can view a patient's file only if the physician has been pre-authorized by the patient. Applicant's invention gives the patient the ability to choose whether or not a particular physician can have access to the patient's files, by allowing the patient to use their system access code to log onto the system and either grant or deny access.

Thus, claim 29 is not anticipated by Joao. Further, because claim 29 is dependent on claim 24, Applicant believes that claim 29 is now in condition for allowance in light of the amendment to claim 24.

(T) As per claim 30, because claim 30 is dependent on claim 24, Applicant believes that claim 30 is now in condition for allowance in light of the amendment to claim 24.

(U) As per claim 31, Applicant respectfully disagrees with the Examiner's conclusion that claim 31 is anticipated by Joao. Joao discloses a database that contains statistical and/or mathematical information for assigning and/or correlating certain levels and/or estimates for any and/or all of the information generated by the central processing computer. (Joao: col. 19, lines 13-20). While Applicant acknowledges that Joao discloses that statistical calculations are contained in the database, Joao does not disclose a system for *performing* medical studies using a group of patient files. Applicant's invention expressly discloses a system whereby patient files can be stored without identifying information. The lack of patient identifiers provides the anonymity necessary for the performance of medical studies without compromising individual patient information and privacy. Thus, claim 32 is not anticipated by Joao. Further, because claim 32 is dependent on claim 24, Applicant believes that claim 32 is now in condition for allowance in light of the amendment to claim 24.

(V) As per claim 32, Applicant respectfully disagrees with the Examiner's conclusion that claim 32 is anticipated by Joao. While Joao discloses a database that can contain information gained from patients and that can be updated by the physician with information derived from patients, Joao does not disclose a system that generates a physician report in computerized form that includes condition-specific information regarding medical practices relating to the specific conditions applicable to the patients. Applicant's invention discloses system that can electrically generate a physician report that includes condition-specific information regarding medical practices relating to the specific conditions applicable to the patients. Among other benefits, this feature saves the physician or provider the time and effort of

having to manually provide such reports. Therefore, Applicant believes that claim 32 is in condition for allowance as it is not anticipated by Joao.

***Regarding the Claim Rejections under 35 U.S.C. 103***

4. Applicant acknowledges the quotation of the appropriate paragraph of 35 U.S.C. 103 that forms the basis for the rejections under this section made in the office action.

5. Claim 7 is rejected under 35 U.S.C. 103(a) over Joao as applied to claim 1-6, 8-13, 16, and 24-32 above, and further in view of Segal (6,754,655; hereinafter Segal). Applicant respectfully disagrees with this obviousness rejection in light of the arguments presented below.

(A) As per claim 7, claim 7 discloses a method that includes the step of electronically generating a pre-visit physician report that includes key questions relating to the patient's condition and the rationale for each question. As stated in paragraph 3F of this response, Joao does not disclose a system that generates key questions relating to the patient's medical condition for the patient to ask the physician. Further, while Segal may describe a system that gives rationale for doing a particular medical test, Segal does not describe a system that provides condition-specific questions for patients to ask their physician and possible responses to these questions for the physician to communicate to the patient. Applicant's invention discloses a system wherein key condition-specific questions are generated and transmitted to the patient. Therefore, because Joao doesn't disclose a system that generates key questions and Segal doesn't disclose providing responses to the questions, it would not have been obvious to one with ordinary skill in the art to provide a method that includes the step of electronically generating a pre-visit physician report that includes key questions relating to the patient's condition and the rationale for each question.

Additionally, as seen in Fig. 18A of the application specification, the information accompanying each of the questions is more accurately described as a "response" to the question

that can be given by the physician to the patient, rather than a "rationale" for the question. As a result, claim 7 was amended to contain the word "response" instead of "rationale." Therefore, Applicant now believes that claim 7 is now in condition for allowance.

6. Claims 14, 15, 17-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Joao as applied to claim 1 above, and further in view of Iliff (5,935,060; hereinafter Iliff). Applicant respectfully disagrees with this obviousness rejection in light of the arguments presented below.

(A) As per claim 14, claim 14 describes a method that allows emergency personnel to securely access patient files in order to treat the patient. Joao does not expressly disclose this method. Iliff describes using a set of login processes for a patient or a patient's assistant to gain access to a database, either using the patient's identification number or the assistant's identification number respectively. (Iliff; col. 5, lines 51-67). Iliff does not expressly disclose or suggest a method that allows emergency personnel to gain access to patient files. Further, Iliff does not expressly disclose or suggest a method that supplies emergency personnel with a *patient's* access code, rather than an access code for the particular emergency personnel, to treat the patient. Applicant's invention discloses a method whereby emergency personnel have access to a patient's files using the patient's access code. This allows a quicker and more effective treatment of the patient in times of emergency. Therefore, it would have not been obvious to one with ordinary skill in art to describe a method that allows emergency personnel to securely access patient files with an access code associated with a patient in order to treat the patient.

Furthermore, claim 14 is dependent on claim 11. Given the amendment adding steps neither disclosed in Joao nor suggested by Iliff to claim 11, Applicant believes that claim 14 is now in condition for allowance.

(B) As per claim 15, claim 15 is dependent on claim 11. Given the amendment adding steps neither disclosed in Joao nor suggested by Iliff to claim 11, Applicant believes that claim 15 is now in condition for allowance.

(C) As per claim 17, Applicant respectfully disagrees that Joao discloses a method for assisting a physician in providing medical services to a patient who has a medical condition including the step of conducting a pre-visit interview of said patient using electronically selected information including interactively interviewing said patient in preparation for a medical consultation. While Joao discloses a database where information can be obtained from patients through questionnaires, forms, narratives, etc... (Joao: col. 19, lines 54-64), Joao does not disclose a method to interview patients using electronically selected information that pertains to the patient's specific condition. Applicant's invention discloses a system wherein the questions asked of the patient can vary in both content and scope depending on responses by the patient to particular questions. For example, if the patient is a female over age 50, questions generated in response to a complaint of hip pain may vary from questions that would be generated if the patient was a 30-year old male. In addition, neither Joao nor Iliff suggests a method for interview patients using electronically selected information that pertains to the patient's specific condition. Thus, it would have not been obvious for one with ordinary skill in the art to include this feature.

Further, while Iliff discloses providing a patient with access information for logging onto a server site and logging onto a server by said patient, there is no suggestion or motivation in Iliff to provide access information for the purpose of the patient to complete a pre-visit interactive interview using electronically selected information specific to the patient's condition. Therefore, Applicant believes claim 17 is in condition for allowance given that it would not have been obvious to one with ordinary skill in the art to include the aforementioned steps.

(D) As per claim 18, because claim 18 is dependent on claim 17, and Applicant believes that claim 17 is in condition for allowance, Applicant also believes that claim 18 is in condition for allowance.

(E) As per claim 19, claim 19 was amended to provide a method that includes the step of providing a plurality of condition-specific key questions to the patient and physician with the pre-visit summary. Neither Joao nor Iliff suggest or disclose condition-specific questions that are

delivered to the patient or physician before a visit. Applicant's invention discloses a system that generates key condition-specific questions that can be transmitted to a patient prior to the visit with the physician. Therefore, Applicant believes that claim 19 is in condition for allowance as it would not have been obvious to one with ordinary skill in the art to include the aforementioned step. Additionally, because claim 19 is dependent on claim 17, and Applicant believes that claim 17 is in condition for allowance, Applicant also believes that claim 19 is in condition for allowance.

(F) As per claim 20, because claim 20 is dependent on claim 17, and Applicant believes claim 17 is in condition for allowance, Applicant believes claim 20 is in condition for allowance.

(G) As per claim 21, because claim 21 is dependent on claim 17, and Applicant believes that claim 17 is in condition for allowance, Applicant also believes that claim 21 is in condition for allowance.

(H) As per claim 22, because claim 22 is dependent on claim 17, and Applicant believes that claim 17 is in condition for allowance, Applicant also believes that claim 22 is in condition for allowance.

(I) As per claim 23, claim 23 discloses a method that includes the step of storing patient files so that the identity of the patients are not disclosed, so that the patient files can be used in performing medical studies. While Joao discloses a database that can be securely accessed by patients and providers, Joao does not disclose a database that allows patient files to be accessed without the person accessing the files knowing which file is being accessed. For example, Joao discloses how identification cards can be used to store pertinent information for any of the *respective* parties so as to provide the *respective* party with access to the various data. (Joao: col. 7, lines 18-23). The Joao system neither discloses nor suggests allowing users to non-discriminately access unidentified patient files for the purposes of performing medical studies. Applicant's invention discloses a system wherein certain specified users can gain access to patient files without compromising the security of each patient's information.

Additionally, as in paragraph 3U of this response, while Applicant acknowledges that Joao discloses that statistical calculations are contained in the database, Joao does not disclose or suggest a system for *performing* medical studies using a group of patient files. Therefore, it would not have been obvious to one with ordinary skill in the art to disclose a method including this step. Furthermore, because claim 23 is dependent on claim 17, and Applicant believes claim 17 is in condition for allowance, Applicant also believes claim 23 is in condition for allowance.

Applicant acknowledges the references cited and relied upon.

### CONCLUSION

All of the objections and rejections raised by the Examiner have been addressed by Applicant. Attorney for Applicant has carefully reviewed each one of the cited references, namely the Joao, Segal, and Iliff patents, and believes that the new claims presently on file in the subject application are patentably distinguishable with respect to the prior art, either taken alone or in combination with one another. In view of the amendments to the disclosure and the remarks submitted herein, Applicant submits that all of the new claims of record are in condition for allowance and respectfully requests that a Notice of Allowance be issued in this case in due course.

If it is felt for any reason that direct communication with Applicant's attorney would serve to advance prosecution of this application to allowance, the Examiner is invited to contact the undersigned, attorney of record in this case, Richard D. Clarke, Esq., at one of the listed below numbers or at his below listed e-mail address.

Dated: October 5, 2005

Respectfully Submitted,

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